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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,471	09/19/2003	Barry Pritchard	F1012/20136	8870
3000 7590 02/19/2008 CAESAR, RIVISE, BERNSTEIN, COHEN & POKOTILOV, LTD. 11TH FLOOR, SEVEN PENN CENTER 1635 MARKET STREET PHILADELPHIA, PA 19103-2212				
EXAMINER DESAI, HEMANT				
ART UNIT 3721		PAPER NUMBER		
NOTIFICATION DATE 02/19/2008		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@crbcp.com

Office Action Summary

Application No.

10/666,471

Applicant(s)

PRITCHARD ET AL.

Examiner

Hemant M. Desai

Art Unit

3721

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 and 47-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 and 47-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/22/2008 has been entered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The new subject matter which was not described in the specification, for example: "a first interface space", line 8, "a second interface space", line 14.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms "a first interface space" (claim 1, line 8) and "a second interface space" (line 14, claim 1) are confusing, because it is not clear which "first and second interface space" applicant is referring to.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-9, 25-36, 47 and 61-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Owensby et al. (5484375) in view of Kurth et al. (20020104290).

Owenby et al. disclose means for forming the series of bags from the web of film (see col. 7, lines 45-50) or equivalent thereof, a tube inserter (36), the tube inserter comprising means to grip respective ones of the series of tube segments and place the respective ones of the sterilized tube segments in the first interface space between the opposing peripheral edge portions of respective ones of the flexible bags (see col. 7, lines 53-62), means for fusing (38) the a portion of the exterior surface of each respective one of the tube segments between the opposing peripheral edge portions of the respective ones of the flexible bags so that the open end of a respective one of the tube segments is in communication with the interior space in a respective one of the

flexible bags and the closed end of each of a respective one of the tube segments is located outside of a respective one of the flexible bags (see col. 7, lines 63-66), and means for filling the hollow interior of each of the sterilized flexible packages with the product through the tube and then means for sealing the packages with the product therein (see col. 8, lines 14-22). "for attaching.....said apparatus", claim 1, lines 1-12, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Owensby et al., as mentioned above, disclose all the claimed limitations, except for the sterile processing chamber to sterilize the fitment and the bag forming process and filling process. However, Kurth et al. disclose that it known to provide a sterilize chamber (6, 7, fig. 1) in which the whole packaging process is being done (see fig. 1) thereby providing sterile packaging process. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the apparatus and method of Owensby et al. for attaching a tube segment to a bag with the sterile processing chamber of Kurth et al. for providing more sterile packaging process.

Regarding claims 25-27 and 61-63, Owensby et al. disclose a bag film splitter (41, fig. 3) that separates the opposing wall portions of the bag film from one another at a tube insertion site prior to the inserter placing tube segment in position (see col. 7, lines 59-63).

Regarding claims 28-35 and 64-66, Owensby et al. disclose that the at least one member comprises at least one sealing jaw for heat sealing the open end of the tube segment between the wall portions of the bag film (see fig. 4).

Regarding claim 47, the modified method of Owensby et al. teaches all the method steps of claim 47.

7. Claims 2-9 and 48-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Owensby et al. and Kurth et al. as applied to claims 1 and 47 above, and further in view of Cicha et al. (5857309).

Regarding claims 2-9, the modified apparatus and method of Owensby et al., as mentioned above, meets all the claimed limitations except for a tube sterilization chamber including a hydrogen peroxide bath. However, Cicha et al. disclose that it is known in the art to provide a tube (fitment) sterilization chamber (50, fig. 1) in which tubing (fitment) from a supply of tubing is introduced, the tube sterilization chamber being in communication with the sterile processing chamber and the sterilization chamber includes a hydrogen peroxide bath (see col. 3, lines 1-50) to supply sterilized the tubing. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the modified apparatus and method of Owensby et al. for attaching a tube segment to a bag with the tube sterilization chamber of Cicha et al. for providing sterile tubing.

8. Claims 10-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Owensby et al. and Kurth et al. as applied to claim 1 above, and further in view of Versteeg (4166412).

The modified apparatus and method of Owensby et al. meets all the limitations of claims 10-21, except for a tube supply unwind stand with a supply of tubing. However, Versteeg discloses that it is known in the art to provide the tube supply unwind stand with a supply of tubing (118, fig. 14). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the tube segment of Owensby et al. with the tube supply unwind stand with a supply of tubing in order to supply continuous supply of tube segments.

Regarding claims 22-24, Versteeg teaches that the inserter (121, fig. 13) comprises opposing jaws that are moveable toward one another to grip an end of tubing from supply of tubing prior to the tubing being cut (122, fig. 14) from the supply of tubing to form the tube segment.

9. Claims 53-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Owensby et al., Kurth et al. and Cicha et al. as applied to claim 48 above, and further in view of Versteeg (4166412).

The modified apparatus and method of Owensby et al. meets all the limitations of claim 53-60, except for a tube supply unwind stand with a supply of tubing. However, Versteeg discloses that it is known in the art to provide the tube supply unwind stand with a supply of tubing (118, fig. 14). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the tube segment of Owensby et al. with the tube supply unwind stand with a supply of tubing in order to supply continuous supply of tube segments.

Regarding claims 57-60, Versteeg teaches that the inserter (121, fig. 13) comprises opposing jaws that are moveable toward one another to grip an end of tubing from supply of tubing prior to the tubing being cut (122, fig. 14) from the supply of tubing to form the tube segment.

Response to Arguments

10. Applicant's arguments with respect to claims 1-36 and 47-66 have been considered but are moot in view of the new ground(s) of rejection.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hemant M. Desai whose telephone number is (571) 272-4458. The examiner can normally be reached on 6:30 AM-5:00 PM, Mon-Thurs..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi I. Rada can be reached on (571) 272-4467. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Hemant M Desai/

Primary Examiner, Art Unit 3721